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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,358

04/16/2004

Fysh Dadd

22409-00065-US

8101

30678

7590

07/06/2009

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EXAMINER

STOKLOSA, JOSEPH A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

07/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,358	Applicant(s) DADD ET AL.	
	Examiner JOSEPH STOKLOSA	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-17,20,21,24-26 and 28-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-17,20,21,24-26 and 28-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/2009 has been entered.

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 8, 14-17, 20, 24, 28-30, 32-35, 39, and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (US 6,119,044) in view of Charvin (US 5,123,422).

6. Kuzma discloses a device, comprising an elongate member including at least one electrode (see for example Figure 1, Abstract), and a tip member extending distally from a distal end of the elongate member (see for example Figure 4). The Kuzma

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reference also discloses the tip as comprising a distally tapered portion and a blunt end portion at a distal end of the tapered portion (see for example Figure 4), and further teaches of the tip member being resiliently flexible (see for example Abstract, col. 11 lines 39-42). It is noted that the device disclosed by Kuzma is inherently capable of resisting fold over of the tip when inserted into the cochlea due to the tapering of the electrode array and the smaller cross-sectional at the proximal tip. Applicant does not claim the tip dimensions including length, radius, etc., therefore Examiner considers the portion disclosed in section L8 of Fig. 4 to be the tip, which is apparently geometrically incapable of folding over itself.

7. In regards to claims 2, 8, 33-34, 39, Examiner takes the position that the tapered portion of the tip, as taught by Kuzma, substantially tapers continuously down to the distal soft tip, where it is seen in Fig. 4 that the tip is tapered as well in that the diameter is decreased from the proximal end of L8 to a smaller diameter at the distal end of L8 (see for example Figures 4, 14).

8. In regards to claims 14, 45, Examiner takes the position that Kuzma teaches the tip member is capable of being integral with the elongate member (see for example Figure 15).

9. In regards to claims 15, 46, Kuzma teaches of the tip member being mounted on the distal end of the elongate member (see for example Figure 14).

10. In regards to claims 16, 47, Kuzma teaches of a tip member that includes a lumen therein (see for example Figure 14).

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11. In regards to claims 17, 48, the Kuzma reference teaches of a device wherein the elongated member includes a lumen therein for allowing a stiffening element to be inserted through said elongate member and for allowing a distal end of said stiffening element to extend into said lumen in said tip member (see for example Figure 16 and Abstract).

12. Examiner interprets the lumen to extend through the carrier body and continue all the way to the distal tip, 37. Kuzma states the straightening stylet is inserted into the channel of the electrode array until the tip of the stylet reaches the distal tip, 14, of the array (Fig. 15, 14; Col. 8, line 1-6).

13. In regards to claims 20, 49, the Kuzma reference teaches of a system wherein the tip member inherently has a substantially uniform bending stress distribution in an axial direction, since the tip is of one material and circular and therefore has uniform bending stress (see for example Figure 4).

14. With regard to claim 29-30, 59-61, Kuzma discloses a tip member (Fig. 4, 37) that is made of LSR-25 supported by the electrode array that is made of LSR-70 (Col. 11, line 22-50). LSR 25 and LSR-70 have substantially the same flexibility with LSR-70 being slightly stiffer.

15. Merriam Webster defines a cantilever as, "a projecting beam or member supported at only one end." Accordingly, the device disclosed by Kuzma sufficiently meets this limitation through the use of a stiffer carrier array body composed of LSR-70.

16. With regard to claim 62, Kuzma discloses the use of a stiffening device stylet (ABSTRACT).

17. Kuzma discloses the invention as claimed including a flexible tip, but fails to teach a conical tapered portion tapering and extending distally from the distal end of the electrode array. Charvin teaches that it is known to have a conical tapering at the distal end of an electrode array as set forth in Figs. 3-5, for providing the predictable results of preventing fold-over of the tip member, facilitating insertion of the electrode array, and conforming to the natural geometry and shape of the cochlea (e.g. Col. 1, line 65-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kuzma with a conical tapered portion tapering and extending distally from the distal end of the electrode array, since such a modification was known in the art to provide the predictable results of preventing fold-over of the tip member, facilitating insertion of the electrode array and providing a more rigid support to facilitate placement, and providing for the electrode array to conform to the natural shape and geometry of the cochlea.

18. Claims 5, 6, 12, 13, 37, 38, 43-44, and 59-62 are rejected under 35 U.S.C. 103(a) as obvious over Kuzma in view of Charvin as applied above.

19. In regards to claim 5-6, and 37-38, Kuzma teaches of a barrel portion having a length (L8) that is 0.3 mm, which Examiner interprets as being about 0.4 mm. Similarly, in regards to claim 6, Kuzma teaches of the barrel portion having a diameter (L6) that is 0.6 mm, which Examiner interprets as being about 0.45 mm in diameter. Or in the

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alternative, Examiner takes the position that the dimensions of claims 5 and 6 would have been obvious modifications to system as taught by Kuzma.

20. In regards to claims 12-13 and 43-44, Examiner takes the position that the blunt end portion of the distal tip can be interpreted as part ellipsoidal or part spherical in shape (see for example Figure 6). Or in the alternative, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Kuzma to include the limitations as specified in claims 12 and 13 to enhance efficiency and effectiveness of the system.

21. Claims 4, 9, 10, 11, 21, 25 –26, 36, 40-42, 50-58, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma in view of Charvin.

22. In regards to claims 4, 21, 25, 26, 36, 50, Kuzma does not specifically teach that the elongate member has a diameter greater than the diameter of tip member's barrel portion; Examiner takes the position that such a configuration is well known in the art. Further, although the Kuzma reference discloses the use of silicone rubber (see for example col. 10 lines 58-62), the reference does not specifically teach of the use of a liquid silicone; however, Examiner takes the position that the use of liquid silicone is well known in the art and a modification of the Kuzma reference to include liquid silicone would have been obvious to one having ordinary skill in the art, since it is known in the art to provide efficient and effective operation.

23. In regards to claims 9-11, 40-42, 51-58 (Examiner interprets the dimensions of claim 9 as the length of the tapered portion of the tip member) Examiner takes the position that although the Kuzma reference teaches of elongated tapered device, it does

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not specifically teach of the exact dimensional parameters as specified in claims; however, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Kuzma with the dimensional parameters as specified in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

24. In regards to claim 31, Kuzma discloses the claimed invention, but fails to disclose an alignment indicator between the carrier body and the tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kuzma, since such a modification would provide for ensuring clean mating between the tip and carrier body. Further Claim 31 is a product by process claim and Kuzma anticipates the final product.

25. With regard to claim 59, Kuzma in view of Charvin discloses the invention as claimed, but fails to teach the dimensions of the conical tapered portion to be 76mm in length and tapering from a diameter of .45 to .2mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kuzma in view of Charvin, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and/or since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would

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have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05).

Response to Arguments

26. Applicant's arguments filed 5/4/2009 have been fully considered but they are not persuasive.

27. Applicant argues Examiner has failed to set forth a *Prima Facie* case of obviousness. Examiner respectfully disagrees. Examiner contends a *Prima Facie* case of obviousness has been sufficiently set forth in accordance with MPEP 2142. Examiner has set forth a case of obviousness based on combining prior art elements according to known methods to yield predictable results (see MPEP 2143 EXEMPLERY RATIONALES (A)).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

28. Applicant argues that Charvin would not in fact prevent fold-over. Examiner respectfully disagrees. Applicant cites the slit/cut outs of the distal portion disclosed by Charvin as evidence that Charvin would in fact no prevent fold over, but rather promote

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fold over. Examiner has relied upon the Charvin reference for showing the **general** conical tapered shape without the slits which provide the predictable results of conforming to the natural shape of the cochlea as well as providing greater strength and prevention of fold over, and **not** the cut out slits.

29. For the sake of argument Examiner considers the slit/cut out members to only allow for minimal bending. In other words Examiner considers fold over to occur once a portion has been rotated (bent) about an axis at least greater than 90 degrees. Charvin discloses slits of minimal angles that would prevent rotation of greater than 90 degrees as clearly seen in Figs. 3-5.

30. Applicant argues that Kuzma in view of Charvin fail to teach “the dimensions and shape of said conical tapered portion of said tip member causes at least a **portion** of said tip member to operate as a constant-strength cantilever beam (added for emphasis).” Examiner respectfully disagrees. Examiner considers a portion of the conical tapered portion, specifically any portion between the cut out slits or in the alternative a portion of the conical tapered portion orientated at 90 degrees radially from the deflection force, to exhibit constant-strength cantilevered beam properties.

Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
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6/30/2009